

REMARKS

Claims 1-18, 20-25, 27 and 29-42 are currently pending.

§ 103(a) Rejection - Gordon in view of Farmer

Claims 1-18, 20-25, 27 and 29-42 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Gordon (USPN 5,763,332) in view of Farmer (WO 01/13956). Applicants respectfully traverse this rejection.

The Examiner has asserted a rejection based on Gordon in view of Farmer. Gordon allegedly teaches a cleansing wipe with a high internal phase inverse emulsion. Farmer allegedly teaches a towelette with Emu Oil and lactic-acid producing bacteria.

However, the Examiner has failed to allege a combination that will result in the presently claimed invention. For at least this reason the rejection is improper.

Specifically, the presently claimed invention relates to, for example, a hygiene tissue that has two parts. A first part has a cleaning liquid. A second part has a preparation of a lactic acid producing bacterial strain and a lipid phase, the preparation having a water activity of 0.30 or less. The first and second parts are separate in different parts of the tissue.

The Examiner has failed to allege a combination that will result in the claimed first and second parts that are separate in different parts of the tissue.

Because the presently claimed tissue has two different parts, the tissue may be used for a two step cleaning process. The cleaning liquid and the bacterial composition are separated to at least two different parts of the hygiene tissue, thereby separating the two functions of the tissue. This allows the use of cleaning liquids which would affect bacterial survival, if not placed in a separate part. Thus, the design of the hygiene tissue is important for the present invention; the cleaning liquid and the bacterial composition are not mixed on the tissue in order to keep the cleaning and lactic acid bacteria transferring functions separated. This protects the bacteria from the cleaning liquid so that the cleaning liquid does not interfere with bacterial survival via the presence of any moisture or agents with antimicrobial activity in the cleaning liquid. This is particularly preferable when a water-based cleaning liquid is used, since contact of the bacteria with water decreases bacterial survival.

In contrast, neither Gordon nor Farmer related to a tissue that enables this two step cleaning process. Neither recognize the need for a cleaning liquid being on a separate/different part of the hygiene tissue from a part with a bacteria/lipid composition. Neither teach or suggest the use of cleaning liquids which may interfere with bacterial survival via the presence of any moisture or agents with antimicrobial activity in the cleaning liquid. Thus, it is improper for the Examiner to interpret the Gordon or Farmer as having a cleaning liquid on a separate/different part of the hygiene tissue from a part with a bacteria/lipid composition. There is simply no teaching or suggestion found in either Gordon or Farmer that relates to the claimed tissue with separate parts, one of which has a cleaning liquid and another with a preparation of lactic acid producing bacteria and a lipid phase, the preparation having a water activity of 0.30 or less.

Further, as noted above, Gordon relates to a high internal phase inverse emulsion. And, Farmer relates to a towelette with Emu Oil and lactic-acid producing bacteria. One skilled in the art would not be motivated to incorporate the Emu Oil/bacteria preparation as part of the high internal phase inverse emulsion of Gordon. The Examiner has noted that the high internal phase inverse emulsion of Gordon comprises waxy lipids and such. The Examiner appears to rely on this disclosure to assert one would be motivated to incorporate the Emu Oil of Farmer as such a lipid. However, in making this modification, the Examiner has made an oversight. One skilled in the art would not be motivated to incorporate an Emu Oil with lactic-acid producing bacteria as the lipid in the high internal phase inverse emulsion of Gordon.

The high internal phase inverse emulsion of Gordon has three components (1) a continuous solidified external lipid; (2) an emulsifier that forms the emulsion when the external lipid phase is fluid; and (3) an internal polar phase dispersed in the external lipid phase. See column 11, lines 62-65. The internal polar phase is disclosed to be preferably water or, alternatively, an alcohol or glycol. See column 13, line 52 to column 14, line 59. One skilled in the art would understand that such an internal polar phase would be harmful to the lactic acid producing bacteria.

Thus, one skilled in the art reading Gordon would not be motivated to incorporate a lactic acid producing bacteria in the high internal phase inverse

emulsion of Gordon. Accordingly, one skilled in the art would not combine Gordon and Farmer in the manner asserted by the Examiner.

Moreover, as asserted above, even if one skilled in the art were to combine modify Gordon in order to incorporate the Emu Oil with lactic-acid producing bacteria of Farmer, there is still no teaching or suggestion found in either Gordon or Farmer that relates to the claimed tissue with separate parts, one of which has a cleaning liquid and another with a preparation of lactic acid producing bacteria and a lipid phase, the preparation having a water activity of 0.30 or less.

§ 103(a) Rejection - Koenig

Claim 21, 23, 29-30, 33-34, 39 and 41 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Koenig (USPAPN 2003/0224034). Applicants respectfully traverse this rejection.

The Examiner has failed to provide a *prima facie* case of obviousness for a rejection based on Koenig.

The legal concept of *prima facie* obviousness is a procedural tool of examination which applies broadly to all arts. It allocates who has the burden of going forward with production of evidence in each step of the examination process. ***The examiner bears the initial burden of factually supporting any prima facie conclusion of obviousness.*** If the examiner does not produce a *prima facie* case, the applicant is under no obligation to submit evidence of nonobviousness. See MPEP § 2142.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. See MPEP § 2142.

The initial burden is on the examiner to provide some suggestion of the desirability of doing what the inventor has done. "To support the conclusion that the

claimed invention is directed to obvious subject matter, ***either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references.*** *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985).

Here, the Examiner has made the bald assertion that "Koenig do not teach the claimed article with sufficient specificity to anticipate the claims, however, it would have been within the purview of the artisan of ordinary skill to produce the claimed personal wipe article in view of the teachings of Koenig." *Office Action* at page 4. This is not a proper rejection.

Claim 21 recites:

A hygiene tissue for cleaning of the skin or the urogenital area and transfer of lactic acid producing bacteria to the skin or the urogenital area, comprising:
at least one first part supplied with at least a cleaning liquid, and
at least one second part supplied with a composition including a preparation of one or more lactic acid producing bacterial strains and a lipid phase comprising at least one lipid, and wherein said preparation of one or more lactic acid producing bacterial strains has a water activity of 0.30 or less,
wherein the at least one first part and the at least one second part are separate in at least two different parts of the hygiene tissue,
wherein the first and second parts are arranged on different sides of the hygiene tissue,
wherein the first part and the second part are separate sheets joined together along two opposite side edges.

Claim 23 recites:

A hygiene tissue for cleaning of the skin or the urogenital area and transfer of lactic acid producing bacteria to the skin or the urogenital area, comprising:
at least one first part supplied with at least a cleaning liquid, and
at least one second part supplied with a composition including a preparation of one or more lactic acid producing bacterial strains and a lipid phase comprising at least one lipid, and wherein said preparation of one or more lactic acid producing bacterial strains has a water activity of 0.30 or less,
wherein the at least one first part and the at least one second part are separate in at least two different parts of the hygiene tissue,
wherein the second part comprises a first sheet and a second sheet joined together along two opposite side edges and the first part comprises a sheet joined to one of said opposite side edges of the second part and extending along said side edge with one of a side edge of the sheet of the first part.

It is quite clear that the Examiner has failed to even allege that Koenig teaches two different and separate parts. Also, the Examiner fails to allege that the tissue comprises a lactic acid producing bacteria. Further, the Examiner fails to allege that (1) the first part and the second part are separate sheets joined together along two opposite side edges, or (2) the second part comprises a first sheet and a second sheet joined together along two opposite side edges and the first part comprises a sheet joined to one of said opposite side edges of the second part and extending along said side edge with one of a side edge of the sheet of the first part.

Koenig does not teach or suggest these omissions. Koenig does not teach or suggest the presently claimed invention, and the burden of supporting a *prima facie* case of obviousness remains with the Examiner.

If the Examiner is to maintain a rejection based upon Koenig, applicants respectfully request that such a rejection detail where support for each of the claim elements can be found in Koenig. Where specific support is missing in Koenig, specific support for why one skilled in the art would be motivated to modify Koenig to arrive at the presently claimed invention is requested.

Conclusion

For the reasons stated above, it is requested that all the rejections be withdrawn and that this application be allowed in a timely manner.

Should any questions arise in connection with this application or should the Examiner feel that a teleconference with the undersigned would be helpful in resolving any issues pertaining to this application, it is requested that the undersigned be contacted at the number indicated below.

Respectfully submitted,

BUCHANAN INGERSOLL & ROONEY PC

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By: _____



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